



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 31 1991

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

SUBJECT: Resubmission of Upgrade of Avian Single-dose Oral LD<sub>50</sub> Study for Pirimiphos Methyl (Actellic 5E Insecticide), Chemical # 010182, MRID 41311001.

FROM: Douglas Urban, Acting Chief  
Ecological Effects Branch  
Environmental Fate and Effects Division (H7507C) 10/31/91

TO: Dennis Edwards, Product Manager (12)  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

The Ecological Effects Branch (EEB) has reviewed the reply of ICI Americas Inc. in regard to the upgrading of a previously submitted acute oral toxicity (LD<sub>50</sub>) test with Pirimiphos Methyl.

Consideration of additional information submitted by ICI Americas Inc. fails to upgrade the subject test from "invalid" to "core" validation category status for the following reasons:

1. The age of test birds was not recorded in the raw data. (as confirmed by ICI Americas, Inc.). An educated guess of the test birds age has been provided based on body weights. All birds should be at least 16 weeks old when testing is initiated.
2. As noted in the previous EEB review, no information was provided in regard to rearing practices which is a current guideline requirement. ICI could not provide this information in their reply.
3. The birds were assigned to treatment groups by sex and weight. Current guidelines require that birds be randomly assigned to treatment groups. Randomization eliminates the possibility of bias, both conscious and unconscious, and forms the basis of any valid statistical test. It also insures that conclusions are valid.



In summary, this test was performed under conditions and procedures that deviated significantly from the currently recommended avian acute oral LD<sub>50</sub> protocol (EPA, Hazard Evaluation Division, Standard Evaluation Procedure, Avian Single-dose Oral LD<sub>50</sub>, June 1985, EPA-540/9-85-001). Number 3 above is uncorrectable and therefore, makes this test unacceptable. EEB cannot complete a risk assessment for the use of Acetellic 5E as a corn seed treatment until an acceptable acute toxicity study is submitted for pirimiphos methyl technical. As of this writing, EEB does not have a "core" avian single-dose oral LD<sub>50</sub> test for pirimiphos methyl technical.

It is recommended that this test be completed with the bobwhite quail, as dietary studies indicate that this species is much more sensitive to pirimiphos methyl than is the mallard. Under 70-1(d), Special Test Requirements, the use of the bobwhite quail is being requested due to the proposed pattern of use - as a seed dressing. The high probability of birds and mammals feeding on treated seed in field environments makes this a legitimate request in order to conduct a thorough risk assessment.

Should you have any questions or require additional information, please contact Art Roybal at 557-1659.

DP BARCODE: D162749

File  
Copy

OCT 21 1991

CASE: 018282  
SUBMISSION: S393221

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 03/22/91  
Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 305 TECH-LBL REV AMND DATA RE  
CHEMICAL: 334300 O-(2-(Dimethylamino)-6-methyl-4-pyrimidinyl) O,O-dimethyl p  
ID#: 010182-00079 ACTELIC 5E INSECTICIDE  
COMPANY: 010182 ICI AMERICAS INC.  
PRODUCT MANAGER: 12 DENNIS JR EDWARDS 703-557-2386 ROOM: CM#2 202  
PM TEAM REVIEWER: RITA KUMAR 703-557-4416 ROOM: CM#2 202B  
RECEIVED DATE: 03/21/91 DUE OUT DATE: 06/19/91

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 162749 EXPEDITE: N DATE SENT: 03/22/91 DATE RET.: / /  
DP TYPE: 001 Submission Related Data Package  
ADMIN DUE DATE: 05/06/91 CSF: N LABEL: N  
ASSIGNED TO DATE IN DATE OUT  
DIV : EFED 03/25/91 / /  
BRAN: EEB / / 10/31/91  
SECT: / / / /  
REVR : / / / /  
CONTR: / / / /

\* \* \* DATA PACKAGE REVIEW INSTRUCTIONS \* \* \*

Please review and comment on upgrading of the avian study.

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
-------	----------------	----------	----------	-----	-----	-------